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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,603	02/05/1999	DAVID T. CUIEL	678503-2012.2	5072

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11/17/2004

FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/245,603

Applicant(s)

CURIEL ET AL.

Examiner

Brian Whiteman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9, 11, 16 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 11, 16, 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: Notice To Comply Sequence letter.

DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/9/04 has been entered.

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Brian Whiteman, Art Unit 1635.

Claims 1-4, 9, 11, 16, and 22-25 are pending.

Applicants' traversal, the addition of claims 24 and 25 and the amendment to claims 1 and 16 filed on 9/9/04 is acknowledged and considered.

Specification

The disclosure is objected to because of the following informalities: on page 54, line 19 there is a DNA sequence with no corresponding SEQ ID NO and Figure 2 has amino acid sequences with no corresponding SEQ ID NOs.

This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the

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attached Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence Disclosures.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9, 11, 16, and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'homologous recombination between a plasmid comprising the fiber gene having a SmaI site and a plasmid comprising a cDNA encoding a tripeptide having the sequence Arg-Gly-Asp (RGD) into the HI loop domain of the fiber knob' in amended claims 1 and 16 and claims dependent therefrom are not supported by the as-filed specification. There appears to be a lack of written description of the claims limitation in the application as filed. See MPEP § 2163.06.

Applicants assert that page 53, lines 7 to 16 of the specification provides support for the recitation of a fiber gene modified by homologous recombination between a plasmid comprising the fiber gene having a SmaI site and a plasmid comprising a cDNA encoding a tripeptide having

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the sequence (RGD) into the HI loop domain of the fiber knob. However, page 53, lines 7-16, is directed to producing a plasmid comprising a modified fiber gene, wherein the fiber gene encodes a tripeptide having the amino acid sequence RGD in the HI loop. In view of the description on page 53, the plasmid was produced by homologous DNA recombination between the plasmid pNEB.PK.FH1RGD and *SwaI* digested pVK50. In view of this recitation on page 53, it appears that the plasmid having a *SwaI* site was linearized with *SwaI* before homologous recombination with pNEB.PK.FH1RGD. The linearized plasmid with no *SwaI* site was used in the homologous recombination step and not a plasmid comprising a fiber gene having a *SwaI* site. The claims are broader than the teaching in the specification directed to using a *SwaI* digested plasmid and a plasmid comprising a cDNA encoding a tripeptide having the sequence RGD into the HI loop domain of the fiber knob.

Thus, nothing in the specification would lead one to the particular combination set forth in the amended claims 1 and 16 and claims dependent therefrom set forth in the instant application. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."

Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 1-4, 9, 11, 16, and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is: the relationship between the adenovirus comprising a modified fiber gene and homologous recombination between a plasmid comprising the fiber gene having a *Swa*I site and a plasmid comprising a cDNA encoding a tripeptide having the sequence Arg-Gly-Asp (RGD) into the HI loop domain of the fiber knob. The claims do not define how the adenovirus is related to either plasmids and what type of modified fiber gene was produced as the result of the homologous recombination between the two plasmids.

Claims 2-4, 9, 11, and 22-25 are rejected under 112 second paragraph because the claims are dependent on either claim 1 or claim 16.

Claims 1 and 16 recite the limitation "the fiber gene having a *Swa*I site" in line 3 and line 4, respectively. There is insufficient antecedent basis for this limitation in the claims.

Claims 2-4, 9, 11, and 22-25 are rejected under 112 second paragraph because the claims are dependent on either claim 1 or claim 16.

Claim 22 recites the limitation "said tumor cell" in line 1. There is insufficient antecedent basis for this limitation in the claim. Suggest replacing the limitation with -- tumor cells --.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

In view of the 112 second paragraph rejections for claim 1 and claims dependent therefrom, set forth above, the claims read on a recombinant adenovirus comprising a modified fiber gene.

Claims 1-4, 9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wickham et al. The previous rejection is maintained for the reasons of record advanced on pages 3-5 of the Office action mailed on 2/26/03.

Applicant's arguments filed 9/9/04 have been fully considered but they are not persuasive. Applicants contend that claim 1 has been clarified to recite a fiber gene modified by homologous recombination between a plasmid comprising the fiber gene having a SmaI site and a plasmid comprising a tripeptide having the sequence Arg-Gly-Asp (RGD) into the HI loop domain of the fiber knob. Applicants contend that Wickham does not teach or suggest generating a fiber gene with a SmaI site.

In view of the 112 second paragraph rejection for the limitation in amended claim 1 and claims dependent therefrom, the examiner asserts that the claimed invention still is directed to a adenovirus comprising a modified fiber gene. The claims as written do not specifically require (or cannot be interpreted to require) that the modified fiber gene of the adenovirus has a SmaI site. As stated in the 112 second paragraph rejection, the claims do not define how the adenovirus comprising a modified fiber gene is structurally related to either plasmid used in the homologous recombination process.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

In view of the 112 second paragraph rejection for claim 16 and claims dependent therefrom, set forth above, the claims read on a recombinant adenovirus comprising a modified fiber gene.

Claims 16, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. The previous rejection is maintained for the reasons of record advanced on pages 6-7 of the Office action mailed on 2/26/03.

Applicants have argued that Wickham has not taught the claimed modified adenovirus as previously discussed under the 102 rejection.

In response, the examiner maintains that Wickham has taught the invention as claimed. See response to applicants' arguments against the 102(e) rejection.

Accordingly, the rejection is maintained for the reasons of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

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